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## **CLAIMS:**

- 1. A process for preparing A1AT from A1AT-containing solutions, comprising the following steps:
  - (a) subjecting an A1AT-containing solution to ion-exchange chromatography;
  - (b) adding detergents and optionally a solvent for inactivating lipidenveloped viruses;
  - (c) followed by increasing the salt concentration to salt out the detergents.
- 2. The process according to claim 1, wherein said A1AT-containing solution has been obtained from blood plasma or its fractions, preferably from a reconstituted plasma fraction IV1 (Cohn), or is derived from a recombinantly or transgenically expressed A1AT preparation or a fermentation supernatant.
- 3. The process according to claim 1 and/or 2, wherein ion-exchange chromatography is performed on an anion-exchange gel, preferably DEAE-Sepharose® or DEAE-Sepharose® Fast Flow.
- 4. The process according to any of claims 1 to 3, wherein said virus inactivation according to step (b) is effected with Triton X-100, Polysorbate 80 (Tween 80), TnBP and/or caprylic acid or caprylate, preferably at final concentrations of ≥ 0.1% (w/w) Triton and Tween 80, ≥ 0.03% (w/w) TnBP, ≥ 0.1 mM caprylic acid or caprylate, with an incubation time of ≥ 0.1 hours, preferably ≥ 1 hour, at ≥ 4 °C, especially at ≥ 15 °C.

- 5. The process according to any of claims 1 to 4, wherein the salt concentration of the solution is brought to  $\geq$  0.5 M in step (c) and particles formed thereby are preferably removed by filtration.
- 6. The process according to any of claims 1 to 5, wherein chromatography on hydrophobic chromatographic materials is performed.
- 7. The process according to any of claims 1 to 6, wherein a treatment of the A1AT-containing fraction with a material which contains heparin in an immobilized form (heparin gel) is performed.
- 8. The process according to any of claims 5 to 7, wherein a further virus inactivation step is performed afterwards, preferably pasteurization in the presence of ≥ 0.5 M sodium citrate, amino acids, sugars or mixtures thereof.
- 9. The process according to any of claims 1 to 8, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration.
- 10. The process according to any of claims 1 to 9, wherein a separation of virus particles is performed, preferrably by nanofiltration, preferably with filters having pore sizes of 15-20 nm.
- 11. The process according to any of claims 1 to 10, wherein the A1AT fraction obtained is stored as a liquid, frozen or freeze-dried preparation.
- 12. A1AT having a purity of > 90%, an activity of ≥ 0.8 PEU/mg in its active form, an IgA content of ≤ 1 mg/ml, a residual detergent content of < 50 ppm, especially < 10 ppm, and a monomer content of > 90%, based on the total amount of A1AT.
- 13. The A1AT according to claim 12, obtainable by a process comprising the following steps:

- reconstitution of plasma fraction IV1 (Cohn);
- anion-exchange chromatography on DEAE-Sepharose® Fast Flow;
- optionally chromatography on a solid phase which comprises heparin in an immobilized form (heparin affinity chromatography);
- optionally hydrophobic interaction chromatography (HIC);
- virus inactivation with ≥ 0.1% (w/w) Triton/≥ 0.03% (w/w) TnBP
  with an incubation time of ≥ 1 hour at ≥ 15 °C;
- addition of salt to increase the ion strength of the solution; and
- removal by filtration of particles formed thereby.
- The A1AT according to claim 13, wherein a further virus inactivation step is performed afterwards, preferably pasteurization in the presence of ≥ 0.5 M sodium citrate, amino acids, sugars or mixtures thereof.
- 15. The A1AT according to claim 13, wherein the ion strength of the solution is preferably reduced by ultra-/diafiltration.
- 16. The A1AT according to claim 13, wherein a virus and/or prion depletion or inactivation step is comprised, preferably a separation of virus particles by nanofiltration, preferably with filters having pore sizes of 15-20 nm.
- 17. The A1AT according to claim 13, wherein the A1AT fraction obtained is stored as a liquid, frozen or freeze-dried preparation.
- 18. A medicament containing an A1AT according to any of claims 12 to 17 as a sole active ingredient or in combination with anti-inflammatory agents, preferably steroids, NSAIDs.

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19. Use of the A1AT according to any of claims 12 to 17 for preparing a medicament for the treatment of A1AT deficiency, degenerative phenomena of the lung, such as lung fibrosis and emphysema.